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| 10/055,760 | 01/23/2002 | Brent Delzer | 60156P1 | 7300 |

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EXAMINER

IBRAHIM, MEDINA AHMED

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,760

Applicant(s)

DELZER, BRENT

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-47 are pending and are under examination.

Claim Objections

Claims 1-2, 20, and 46 (and dependents 3-19, 21-45 and 47) are objected to for failing to recite complete ATCC accession information. The claims should be amended to recite the accession information as appropriate.

Claims 5 and 18 are objected to because "a plant according to claim 2" and "a maize plant according to claim 2", respectively, lack proper article. It is suggested that "a" in line 2 of claim 5 and line 1 of claim 18, is replaced with ---the---.

Claim 8 lacks proper article. "A" should be changed to --The--.

In claim 18, depending upon claim 2, "plants " in line 3, should be changed to ---the maize plant---.

In claim 19, "A" should be changed to ---The---, for proper article.

Claims 26-28, "A" should be changed to ---The---, for proper article.

Claims 36-38, "A" should be changed to ---The---, for proper article.

In claim 47, "said a single gene trait" should be changed to ---said single gene trait---, for clarification.

Claims 36 and 26 don't further limit parent claims 35 and 25, respectively, because of "or" in line 3 of the parent claims.

Objection to the specification

The specification is objected to for reciting incomplete ATCC accession information in page 23, line 5. The specification is also objected to for the inclusion of a

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hyperlink directed to an Internet address, in page 19, line 19, and page 16, line 1, for example. The use of hyperlinks is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation "NP222". Since the name "NP222" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "NP222" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1-2, 20 and 46 to recite the ATCC deposit number in which seed of maize inbred line NP222 has been deposited would overcome the rejection.

In claim 46, a "single gene trait" is unclear, as the term does not carry with it any limitation as to the structural or physiological properties of the gene. The sentence on

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page 17, lines 1-2, recites, "the genes responsible for a single gene trait...(emphasis added) which indicates that more than one gene confers the single gene trait. The specification does not clearly define a "single gene trait", and therefore, the term is open to a variety of interpretations.

In claim 10, "the line PH2EJ" lacks antecedent basis.

Claim 16, depending from claim 6, is confusing in the recitation of "wherein said Cry1Ab gene is introgressed into said maize plant..." because it is unclear as to whether the maize plant transformed with the CryAb gene is the same plant as that received the same gene by introgression. The metes and bounds of the claim are unclear.

In claim 19, what is encompassed in "being protoplasts or callus derived therefrom" is unclear

Claims 21, 31 and 45 are indefinite in the recitation of "good", "acceptable to good", "above average", and "reliable" which are relative terms lacking comparative basis.

Claims 25 and 35 are indefinite for lacking correlation between the preamble and last method step. The preamble recites a method for producing maize seed, and the resultant product is first generation maize seed.

Claims 22, 32 and 46 are indefinite for lacking defined method steps. The claims are also indefinite in the recitation of "using" (claims 22, 32 and 46) and "employing" (claim 22 and 32) without any positive method steps by which one could practice the claimed method.

Claim 23 is indefinite in the recitation of "The maize plant breeding program of claim 22", because claim 22 is drawn to a method for developing a maize plant rather than a breeding program.

Claim 33 is indefinite in the recitation of "The maize plant breeding program of claim 32, because claim 32 is drawn to a method for developing a maize plant rather than a breeding program.

Claim 41 is indefinite because it is unclear what the method is for. The preamble is incomplete. Dependent claims 44-45 are included in the rejection.

Claim 42 is indefinite for lacking correlation between the preamble and last method step. The preamble recites a method for producing maize plant, and the resultant product is progeny maize seed. Also, step c indicates that one obtains seed by growing a seed.

Claims 25 and 35 are indefinite for lacking correlation between the preamble and last method step. The preamble recites a method for producing maize seed, and the resultant product is first generation maize seed.

Claims 43 is indefinite in the recitation of "said maize plant of method 42". If Applicant intends ---the maize plant of claim 42---, then, it is unclear if maize plant is produced by the method of claim 42 (progeny maize seed is produced rather than a maize plant). The claim is also indefinite in the recitation of additional "NP222-derived" plants or seeds. Would "derived" mean "isolated" or "progeny" or something else? What is encompassed in the derived plant/seed is unclear. Dependent claims 44-45 are included in the rejection. Also, parent claim 42 does mention any NP222 derived plants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 23 of the specification indicating that Applicants have made a deposit of the claimed inbred maize line NP222 with the ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. No ATCC deposit Accession information is provided.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit

requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Enablement

Claims 16 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for introgressing a single gene trait into a maize plant of inbred line NP222 via breeding methods.

Applicant has not disclosed or provided guidance for the introgression of a single gene trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, Applicant has not provided guidance regarding the genetic or the morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait (column 3, lines 26-46). Kraft et al (Theor. Appl. Genet. 2000, vol. 101, pp. 323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and such that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See, Eshed et al (Genetics, vol. 143, pp1807-

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1817, 1996) who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effect are not common in maize breeding materials, such that one or more transgenes can be transferred from one genetic background to another.

Therefore, given the lack of guidance in Applicants' specification regarding transfer and expression of genes by backcrossing into Applicant's maize line while retaining the other desirable genotypic and phenotypic characteristics, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, one skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 6-17, 21-24, 29-34, and 39-41 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to maize plants of an undisclosed number of generations that are only known to have at least one ancestor of NP222 maize plant,

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NP222-derived plants/seed obtained by repeated crossing of a NP222 maize plant or with another non-NP222 maize plant by a number of generations. These are genus claims. Applicant only describes inbred maize line NP222 having specific combination of genotypic and phenotypic characteristics. Applicant has not described the morphological and/or genotypic characteristics for all hybrid maize plants and seeds of claims 29-30 and 39-40 produced by crossing the inbred maize line NP222 with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish F1 hybrid maize plants/seeds from other maize plants and seeds are described. Since Applicant has not described even F1 generation plants and seed, methods for using F1 hybrid plant/seed or inbred plant NP222 as a source of breeding material or as an ancestor as claimed in claims 22-23, 32-33 and 42-43 to produce subsequent generation plants of claims 21, 24, 31, 34 and 44-45 are similarly not described. Furthermore, since Applicant has not described the breeding partners involved in crossing with the exemplified plant, or the resultant product, Applicant also has not described methods for using the products in subsequent generations of outcrossing to uncharacterized breeding partners, or the resultant products of said multiple outcrosses. See claims 21, 31 and 45. The only characteristics recited in the claims for the plants of claims 21, 31, and 45 are the expression of the combination of at least two traits which were described with relative terms that lack comparative basis (see rejection under 112, 2nd paragraph).

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the

claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". *Id.* In the instant application, the disclosure of a single maize inbred line, NP222, does not provide adequate written description for the claimed genus, F1 or subsequent generation plants or a method for using them to produce NP222-derived or further derived plants, wherein only one ancestor of the plant is known to be NP222, and the rest of the ancestors are unknown. In addition, because various breeding techniques (claims 22-23, 32-33) and a number of uncharacterized breeding partners and breeding generations have been employed, substantial variation in structure and phenotypes are expected among the resultant plants.

Claims 6-10 and 46 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes and single gene traits or their phenotypic effects in particular maize genetic background. In addition, the claims do not characterize the sequence or identity of the transgenes and single gene traits or recite phenotypic effects. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written

Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Kramer (US 5, 929, 313).

The claim is interpreted as being drawn to a method for producing a progeny maize plant by crossing a first parent plant with a second parent plant, harvesting and growing the first generation seed to yield a progeny maize plant.

Kramer teaches a method for producing hybrid maize plants by crossing the inbred maize line PHMJ2 with another maize plant, harvesting F1 seeds and growing said F1 seed to produce hybrid plants. Kramer teaches all claim limitations.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Puskaric (US 5, 977, 456)

Claims are drawn to inbred maize line designated as "NP23126", plants/ seeds thereof and progeny plant/seed including F1 hybrid produced by crossing the inbred maize line NP222 with unidentified maize lines. The claims are also drawn to maize plant of the inbred line NP222 further comprising transgenes and single gene traits. Breeding and tissue culture of said inbred line and methods, and method for producing maize plants/seeds are also claimed.

Puskaric teaches plants and seed of an inbred maize line designated "PH1M7," and plants having all of the physiological and morphological characteristics of PH1M7 produced from tissue culture (columns 11-16, Table 1; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH1M7, given that they exhibit similar traits associated with plant morphology such as leaves with medium green color, red cob, and agronomic characteristics such as high yield, good seedling vigor and resistance to insect and other diseases resistance (col. 10, lines 47-59). Alternatively, if the claimed plants, plant parts, and seeds of NP222 are not identical to PH1M7, then it appears that PH1M7 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor

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morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH1M7. Puskari also teaches methods to transfer genes that confer desired agronomic traits such as herbicide and insect resistance (see specific genes in columns 21-22) to plant PH1M7, production of tissue culture of regenerable cells from a plant of line PH1M7, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of PH1M7 that is capable of expressing all of the morphological and physiological traits of PH1M7; methods for producing hybrid seeds and plants wherein a plant of inbred line PH1M7 is crossed with another inbred corn plant, and the ensuing seed are harvested, or wherein the method further comprises utilizing plant tissue culture methods to derive progeny; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; method for producing PH1M7 inbred comprising planting a collection of seed of PH1M7 and a hybrid, one of whose parents is PH1M7, and identifying inbred PH1M7 by decreased vigor or identifying seed or the inbred plants with homozygous genotype; PH1M7 comprising transgenes operably linked to regulatory elements, introduced via genetic engineering or breeding, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene; and crossing two corn plants wherein either one or both parents is PH1M7, and crossing the resultant plant with itself or another corn plant to derive further progeny, and repeating such crossing multiple times; and an F₁ hybrid produced by crossing PH1M7 with another, different inbred (columns 1-3, 15-16 and 20-22; claims).

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Therefore, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Puskaric. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Remarks

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

5/2/03

Mai


ASHWIN D. MEHTA, PH.D.
PATENT EXAMINER